

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gerald Horn
Appl. No.: 09/705,526
Conf. No.: 6897
Filed: November 3, 2000
Title: METHOD AND COMPOSITION WHICH REDUCES STIMULATION OF
MUSCLES WHICH DILATE THE EYE
Art Unit: 1614
Examiner: Z. Fay
Docket No.: 114309-1004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED
OCT 16 2003
TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached RTO-1449 form, copies of which are enclosed, be made during the course of examination of the above-identified application for United States patent.

U.S. PATENT DOCUMENTS

<u>Document No.</u>	<u>Date</u>	<u>Inventor</u>
4,515,295	May 7, 1985	Dougherty
4,629,456	December 16, 1986	Edwards
4,834,727	May 30, 1989	Cope
4,906,613	March 6, 1990	Watkins
5,059,188	October 22, 1991	Goddard
5,134,124	July 28, 1992	Nisato et al.
5,514,118	May 7, 1996	Kummer et al.
5,584,823	December 17, 1996	Valberg
5,591,426	January 7, 1997	Dabrowski et al.
5,627,611	May 6, 1997	Scheiner
5,792,767	August 11, 1998	Meyer et al.
5,891,882	April 6, 1999	Meyer et al.
5,891,913	April 6, 1999	Sallmann et al.

<u>Document No.</u>	<u>Date</u>	<u>Inventor</u>
5,895,654	April 20, 1999	Hartford
6,046,207	April 4, 2000	Meyer et al.
09/675,988	September 29, 2000	Horn
09/705,526	November 3, 2000	Horn
6,291,498	September 18, 2001	Horn
6,420,407	July 16, 2002	Horn
2002/0082288	June 27, 2002	Horn
6,515,006	February 4, 2003	Horn

OTHER DOCUMENTS

Bedford Laboratories, *Phentolamine Mesylate for Injection, USP*, May 1999.

Van Alphen, G., *The adrenergic receptors of the intraocular muscles of the human eye*, Investigative Ophthalmology, June 1976, Vol. 15, No. 6, pp. 502-505.

Yoshitomi, T., et al., *Adrenergic Excitatory and Cholinergic Inhibitory Innervations in the Human Iris Dilator*, Exp. Eye Res. 1998, Vol. 40, pp. 453-459.

Lee, Y.C., et al., *Influence of dioptric correction and pupil size on visual function*, J. Cataract Refract. Surg., 2003, Vol. 29, pp. 769-777.

Thorsden, J.E., et al., *Effect of Brimonidine Tartrate Ophthalmic Solution 0.15% on Pupil Diameter in Normal Eye*, April 25, 2003.

Padma-Nathan, H., et al., *Long-term safety and efficacy of oral phentolamine mesylate (Vasomar) in men with mild to moderate erectile dysfunction*, International Journal of Impotence Research, August 2002, Vol. 14, No. 4., pp. 266-270.

Heller, P.H., et al., *Autonomic components of the human pupillary light reflex*, Investigate Ophthalmology & Visual Science, Vo. 31, No. 1, January 1990, pp. 156-162.

King, V.M., *Effects of mydriatics and a miotic on ocular discomfort and pupil responses*, Journal of the American Optometric Association, Vol. 47, No. 7, July 1976, pp. 937-942.

Hill, C.E., et al., *Specificity of Innervation of Iris Musculature by Sympathetic Nerve Fibres in Tissue Culture*, Pflügers Arch., 1976, Vol. 361, pp. 127-134.

Lograno, M.D., et al., *Receptor-responses in fresh human ciliary muscle*, Br. J. Pharmac., 1986, Vol. 87, pp. 379-385.

Zetterström, C., et al., *Pharmacological Characterization of Human Ciliary Muscle Adrenoceptors in Vitro*, Exp. Eye Res., 1988, Vol. 46, pp. 421-430.

Takayanagi, I., et al., *α_{1B} -Adrenoceptor Mechanisms in Rabbit Iris Dilator*, Japan. J. Pharmacol., 1992, Vol. 59, pp. 301-305.

Ishikawa, H., et al., *Comparison of post-junctional α -adrenoceptors in iris dilator muscle of humans, and albino and pigmented rabbits*, Naun. Schmed., 1996, Vol. 354, pp. 165-172.

Yu, Y., et al., *α_{1A} -Adrenoceptors Mediate Sympathetically Evoked Pupillary Dilation in Rats*, JPET, February 2002, Vol. 300, Issue 2, pp. 521-525.

Benson, G.S., et al., *Is Phentolamine Stable in Solution with Papaverine*, The Journal of Urology, November 1988, Vo. 140, pp. 970-971.

Hadzija, B.W., et al., *Physicochemical Stability of Papaverine Hydrochloride-phentolamine Mesylate Mixtures used for Intracavernous Injection: A Preliminary Evaluation*, The Journal of Urology, January 1988, Vol. 140, pp. 64-65.

Soli, M., et al., *Vasoactive Cocktails for Erectile Dysfunction: Chemical Stability of PGE1, Papaverine and Phentolamine*, The Journal of Urology, August 1998, Vol. 160, pp. 551-555.

Tu, Y.H., et al., *Stability of papaverine hydrochloride and phentolamine mesylate in injectable mixtures*, American Journal of Hospital Pharmacy, Vol. 44, November 1987, pp. 2524-2527.

Wang, D.P., et al., *Degradation Kinetics of Phentolamine Hydrochloride in Solution*, Journal of Pharmaceutical Sciences, November 1988, Vol. 77, No. 11, pp. 972-976.

H. Uusitalo, *An acute ocular inflammatory reaction induced by intravitreal bovine serum albumin in presensitized rabbits: the effect of phentolamine*, Acta. Ophthalmol. (Copenh), August 1994, Vol. 63, No. 4, pp. 636-642.

H. Uusitalo, *The effect of autonomic receptor blockers on the ocular response to topical chemical irritation*, Acta. Physiol. Scand., May 1984, Vol. 121, No. 1, pp. 1-8.

Davies, NM: *Biopharmaceutical considerations in topical ocular drug delivery*, Clin. Exp. Pharmacol. Physiol., 2000, Vol. 27, No. 7, pp. 558-562.

Alster, Y., et al., *Dapiprazole for patients with night haloes after excimer keratectomy*, Graefe's Arch. Clin. Exp. Ophthalmol., 1996, Vol. 234, pp. S139-S141.

McDonald II, J.E., et al., *Effect of brimonidine tartrate ophthalmic solution 0.2% on pupil size in normal eyes under different luminance conditions*, J. Cataract Refract. Surg., April 2001, Vol. 27, pp. 560-564.

O'Brart, D.P.S., et al., *Disturbances in night vision after excimer laser photorefractive keratectomy*, Eve, 1994, Vol. 8, pp. 46-51.

Fan-Paul, N.I., et al., *Night Vision Disturbances After Corneal Refractive Surgery*, Survey of Ophthalmology, November-December 2002, Vol. 47, No. 6, pp. 533-546.

Connor, C.G., et al., *The clinical efficacy of Rev-Eyes™ in reversing the effects of pupillary dilation*, Journal of the American Optometric Association, J. Am. Optom. Assoc., 1993, Vol. 64, pp. 634-636.

O'Brart, D.P.S., et al., *Night vision after excimer laser photorefractive keratectomy: haze and halos*, European Journal of Ophthalmology, 1994, Vol. 4, No. 1, pp. 43-51.

Nielsen, C.B., et al., *Effect of α - and β -receptor active drugs on corneal thickness*, Acta Ophtahl., 1985, Vol. 63, pp. 351-354.

Goodman & Gillman's *The Pharmacological Basis of Therapeutics*, (Ninth Edition) at pp. 225-232.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

BELL, BOYD & LLOYD LLC



BY _____
Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

Dated: October 9, 2003

INFORMATION DISCLOSURE CITATION IN AN APPLICATION <small>(Use several sheets if necessary)</small> <small>O I P E</small> <small>OCT 14 2003</small> <small>PTO Form 1449</small>		Atty Docket No. 114309-1004	Application No. 09/705,526
		Applicant Gerald Horn	
		Filing Date Nov. 3, 2000	Group 1614

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
	4,515,295	05-07-85	Dougherty			
	4,629,456	12-16-86	Edwards			
	4,834,727	05-30-89	Cope			
	4,906,613	03-06-90	Watkins			
	5,059,188	10-22-91	Goddard			
	5,134,124	07-28-92	Nisato et al.			
	5,514,118	05-07-96	Kummer et al.			
	5,584,823	12-17-96	Valberg			
	5,591,426	01-07-97	Dabrowski et al.			
	5,627,611	05-06-97	Scheiner			
	5,792,767	08-11-98	Meyer et al.			
	5,891,882	04-06-99	Meyer et al.			
	5,891,913	04-06-99	Sallmann et al.			
	5,895,654	04-2099	Hartford			
	6,046,207	04-04-00	Meyer et al.			
	09/675,988	09-29-00	Horn			
	09/705,526	11-03-00	Horn			
	6,291,498	09-18-01	Horn			
	6,420,407	07-16-02	Horn			
	2002/0082288	06-27-02	Horn			
	6,515,006	02-04-03	Horn			

FOREIGN PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Country	Class	Subclass	Translation
						Yes No

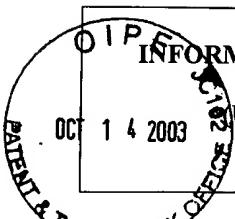
Examiner:	Date Considered:
<small>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>	

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) CT 14 2003 PTO Form 1449		Atty Docket No. 114309-1004	Application No. 09/705,526
		Applicant Gerald Horn	
		Filing Date Nov. 3, 2000	Group 1614

Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Bedford Laboratories, Phentolamine Mesylate for Injection, USP, May 1999.
	Van Alphen, G., <i>The adrenergic receptors of the intraocular muscles of the human eye</i> , Investigative Ophthalmology, June 1976, Vol. 15, No. 6, pp. 502-505.
	Yoshitomi, T., et al., Adrenergic Excitatory and Cholinergic Inhibitory Innervations in the Human Iris Dilator, Exp. Eye Res. 1998, Vol. 40, pp. 453-459.
	Lee, Y.C., et al., <i>Influence of dioptic correction and pupil size on visual function</i> , J. Cataract Refract. Surg., 2003, Vol. 29, pp. 769-777.
	Thordsen, J.E., et al., Effect of Brimonidine Tartrate Ophthalmic Solution 0.15% on Pupil Diameter in Normal Eye, April 25, 2003.
	Padma-Nathan, H., et al., <i>Long-term safety and efficacy of oral phentolamine mesylate (Vasomar) in men with mild to moderate erectile dysfunction</i> , International Journal of Impotence Research, August 2002, Vol. 14, No. 4., pp. 266-270.
	Heller, P.H., et al., <i>Autonomic components of the human pupillary light reflex</i> , Investigate Ophthalmology & Visual Science, Vo. 31, No. 1, January 1990, pp. 156-162.
	King, V.M., <i>Effects of mydriatics and a miotic on ocular discomfort and pupil responses</i> , Journal of the American Optometric Association, Vol. 47, No. 7, July 1976, pp. 937-942.
	Hill, C.E., et al., <i>Specificity of Innervation of Iris Musculature by Sympathetic Nerve Fibres in Tissue Culture</i> , Pflügers Arch., 1976, Vol. 361, pp. 127-134.
	Lograno, M.D., et al., <i>Receptor-responses in fresh human ciliary muscle</i> , Br. J. Pharmac., 1986, Vol. 87, pp. 379-385.
	Zetterström, C., et al., <i>Pharmacological Characterization of Human Ciliary Muscle Adrenoceptors in Vitro</i> , Exp. Eye Res., 1988, Vol. 46, pp. 421-430.
	Takayanagi, I., et al., <i>α-_{1B}-Adrenoceptor Mechanisms in Rabbit Iris Dilator</i> , Japan. J. Pharmacol., 1992, Vol. 59, pp. 301-305.
	Ishikawa, H., et al., <i>Comparison of post-junctional α-adrenoceptors in iris dilator muscle of humans, and albino and pigmented rabbits</i> , Naun. Schmed., 1996, Vol. 354, pp. 165-172.
	Yu, Y., et al., <i>α-_{1A}-Adrenoceptors Mediate Sympathetically Evoked Pupillary Dilation in Rats</i> , JPET, February 2002, Vol. 300, Issue 2, pp. 521-525.
	Benson, G.S., et al., <i>Is Phentolamine Stable in Solution with Papaverine</i> , The Journal of Urology, November 1988, Vo. 140, pp. 970-971.
	Hadzija, B.W., et al., <i>Physicochemical Stability of Papaverine Hydrochloride-phentolamine Mesylate Mixtures used for Intracavernous Injection: A Preliminary Evaluation</i> , The Journal of Urology, January 1988, Vol. 140, pp. 64-65.

Examiner:	Date Considered:
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

RECEIVED
OCT 16 2003
TECH CENTER 1600/2000


INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

OCT 14 2003

PTO Form 1449

Atty Docket No. 114309-1004	Application No. 09/705,526
Applicant Gerald Horn	
Filing Date Nov. 3, 2000	Group 1614

Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Soli, M., et al., <i>Vasoactive Cocktails for Erectile Dysfunction: Chemical Stability of PGE1, Papaverine and Phentolamine</i> , The Journal of Urology, August 1998, Vol. 160, pp. 551-555.
	Tu, Y.H., et al., <i>Stability of papaverine hydrochloride and phentolamine mesylate in injectable mixtures</i> , American Journal of Hospital Pharmacy, Vol. 44, November 1987, pp. 2524-2527.
	Wang, D.P., et al., <i>Degradation Kinetics of Phentolamine Hydrochloride in Solution</i> , Journal of Pharmaceutical Sciences, November 1988, Vol. 77, No. 11, pp. 972-976.
	H. Uusitalo, <i>An acute ocular inflammatory reaction induced by intravitreal bovine serum albumin in presensitized rabbits: the effect of phentolamine</i> , Acta. Ophthalmol. (Copenh), August 1994, Vol. 63, No. 4, pp. 636-642.
	H. Uusitalo, <i>The effect of autonomic receptor blockers on the ocular response to topical chemical irritation</i> , Acta. Physiol. Scand., May 1984, Vol. 121, No. 1, pp. 1-8.
	Davies, NM: <i>Biopharmaceutical considerations in topical ocular drug delivery</i> , Clin. Exp. Pharmacol. Physiol., 2000, Vol. 27, No. 7, pp. 558-562.
	Alster, Y., et al., <i>Dapiprazole for patients with night haloes after excimer keratectomy</i> , Graefe's Arch. Clin. Exp. Ophthalmol., 1996, Vol. 234, pp. S139-S141.
	McDonald II, J.E., et al., <i>Effect of brimonidine tartrate ophthalmic solution 0.2% on pupil size in normal eyes under different luminance conditions</i> , J. Cataract Refract. Surg., April 2001, Vol. 27, pp. 560-564.
	O'Brart, D.P.S., et al., <i>Disturbances in night vision after excimer laser photorefractive keratectomy</i> , Eve, 1994, Vol. 8, pp. 46-51.
	Fan-Paul, N.I., et al., <i>Night Vision Disturbances After Corneal Refractive Surgery</i> , Survey of Ophthalmology, November-December 2002, Vol. 47, No. 6, pp. 533-546.
	Connor, C.G., et al., <i>The clinical efficacy of Rev-Eyes™ in reversing the effects of pupillary dilation</i> , Journal of the American Optometric Association, J. Am. Optom. Assoc., 1993, Vol. 64, pp. 634-636.
	O'Brart, D.P.S., et al., <i>Night vision after excimer laser photorefractive keratectomy: haze and halos</i> , European Journal of Ophthalmology, 1994, Vol. 4, No. 1, pp. 43-51.
	Nielsen, C.B., et al., <i>Effect of α- and β-receptor active drugs on corneal thickness</i> , Acta Ophthalmol., 1985, Vol. 63, pp. 351-354.
	Goodman & Gillman's <i>The Pharmacological Basis of Therapeutics</i> , (Ninth Edition) at pp. 225-232.

RECEIVED

OCT 16 2003

TECH CENTER 1600/2900

Examiner:

Date Considered:

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.